

REMARKS

The applicants have studied the Office Action dated September 19, 2002, and have made amendments to the claims. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 5, 6, and 20 have canceled without prejudice or disclaimer, and claims 1, 2, 18, 21, and 34 have been amended; thus, claims 1-4, 7-19, 21-24, and 34-36 are pending. Consideration and allowance of all the pending claims in view of the above amendments and the following remarks are respectfully requested.

It is noted with appreciation by the applicants that claims 18 and 19 have been indicated as being allowable if rewritten in independent form to include the limitations of the base claim and any intervening claims. Claim 18 has been rewritten into such independent form, and claim 19 depends from claim 18. Accordingly, it is respectfully submitted that claims 18 and 19 are now in condition for allowance.

The applicants also note with appreciation that claims 21-24 have been indicated as being allowable if rewritten to overcome the rejection under 35 U.S.C. § 112, second paragraph, and also if rewritten in independent form to include the limitations of the base claim and any intervening claims. The Examiner indicated that the term "linear actuation member" in claims 21-24 lacked proper antecedent basis because initial recitation of the term "linear actuation member" in claim 20 was couched in functional language. The applicants have amended claim 21 to provide proper antecedent basis for the term "linear actuation member" in claims 21-24. The applicants have also rewritten claim 21 into independent form, and claims 22-24 depend from claim 21. Therefore, withdrawal of the rejection of claims 21-24 under 35 U.S.C. § 112, second paragraph, is respectfully requested. Further, it is respectfully submitted that claims 21-24 are now in condition for allowance.

The Examiner required that Figures 1-3b be amended to include a legend such as "Prior Art". The applicants have amended the drawings as indicated in red on the attached copies of Figures 1-3b. Therefore, it is respectfully requested that the objection to the drawings be

withdrawn, and the requirement for new formal drawings be held in abeyance until receipt of a Notice of Allowance.

The Examiner also objected to the specification because the serial number was not included. The applicants have amended the specification as required by the Examiner. Accordingly, withdrawal of the objection to the specification is respectfully requested.

Claim 2 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner indicated that claim 2 was indefinite because it was not clear what applicants were trying to say. The applicants have amended claim 2 to clarify that the first side of the second member is in a generally parallel, spaced-apart relationship with the external proximate side of the first member. Therefore, withdrawal of the rejection of claim 2 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 1, 2, 4-9, 20, and 34-36 were rejected under 35 U.S.C. § 102(e) as being anticipated by Butcher et al. With respect to claims 5, 6, and 20, these claims have been canceled without prejudice or disclaimer; thus, this rejection is now moot. With respect to claims 1, 2, 4, 7-9, and 34-36, this rejection is respectfully traversed.

Embodiments of the present invention are directed to an apparatus for dispensing a medication fluid, which includes a reservoir and a piston. The reservoir is adapted to contain the fluid and is adapted for use with a drive system having a linear actuation member. Referring to Figs. 14-17, the piston includes a first member 1404 having an external proximate side 1501 and an external distal side 1505. The first member 1404 is adapted to be slidably mounted within the reservoir 406 and to form a fluid-tight barrier within the reservoir 406. The external proximate side 1501 of the first member 1404 is adapted to contact the fluid and is made of a material having a first stiffness, and the external distal side 1505 of the first member 1404 is adapted to be releasably coupled to the linear actuation member. The piston also includes a second member 1201 having a first side 1601 and a second side 1602. The second member 1201 is entirely contained within the first member 1404 and is adapted not to contact the fluid. Referring to Figs.

15c and 17, no portion of the second member 1201 extends beyond the external proximate side 1501 or external distal side 1505 of the first member 1404. In the illustrated embodiments, the second member 1201 is removable from the first member 1404. However, in other embodiments, the first member 1404 may be constructed with no openings or cavities, and the second member 1201 may be encased within the first member 1404 such that the second member 1201 is not removable from the first member 1404 (see Specification, page 22, lines 2-6). Further, the first side 1601 of the second member 1201 is adjacent to the external proximate side 1501 of the first member 1404, and is made of a material having a stiffness that is greater than the first stiffness. As a result, the second member provides stiffness to the first member, and reduces undesirable deformation of the piston.

Amended claim 1, and claims 2, 4, and 7-9 depending therefrom, recite “the second member being entirely contained within the first member and being adapted not to contact the fluid.” Amended claim 34, and claims 35-36 depending therefrom, recite similar language. The Butcher et al. reference fails to disclose, teach, or suggest a piston including a second member that is entirely contained within a first member and is adapted not to contact the fluid, as recited in the claims.

The Butcher et al. reference is directed to a composite piston for a hypodermic syringe. Referring to Figs. 1 and 9, the piston 2 includes an elastic outer sheath 10 (first member) and a rigid inner sheath 4 (second member). However, the outer sheath 10 partially enshrouds the inner sheath 4, and thus, the inner sheath 4 is not entirely contained within the outer sheath 10 (col. 6, lines 27-29). Further, the inner sheath 4 is not protected from contact with the fluid, but is exposed to the fluid in the syringe barrel 62. Therefore, the Butcher et al. reference does not disclose a piston including a “second member being entirely contained within the first member and being adapted not to contact the fluid,” as recited in the claims (emphasis added).

Accordingly, withdrawal of the rejection of claims 1, 2, 4-9, 20, and 34-36 under 35 U.S.C. § 102(e) is respectfully requested.

Claims 1-5, 7-10, and 20 were rejected under 35 U.S.C. § 102(b) as being anticipated by Namey, Jr. With respect to claims 5 and 20, these claims have been canceled without prejudice or disclaimer; thus, this rejection is now moot. With respect to claims 1-4 and 7-10, this rejection is respectfully traversed.

Amended claim 1, and claims 2-4 and 7-10 depending therefrom, recite “the external distal side [of the first member] being adapted to be releasably coupled to the linear actuation member” and “the second member being entirely contained within the first member.” The Namey Jr. reference fails to disclose, teach, or suggest a piston including a first member that is adapted to be releasably coupled to a linear actuation member and a second member that is entirely contained within the first member, as recited in the claims.

The Namey, Jr. reference discloses a plunger used in a syringe. Referring to Figs. 2 and 3, the plunger 20 includes a rubber exterior 32 (first member) overmolded onto a hard plastic core 30 (second member). However, the rubber exterior 32 is not adapted for attachment to the plunger drive ram; instead, a button 26 extends from the proximal end 24 of the plastic core 30 for attachment to the plunger drive ram (col. 3, lines 2-7). Further, the plastic core 30 is not entirely contained within the rubber exterior 32; instead, the rubber exterior 32 only envelops the distal end 22 of the plastic core 30, and the proximal end 24 of the plastic core 30 is exposed (col. 3, lines 9-20). Thus, the Namey Jr. reference does not disclose a piston with “the external distal side [of the first member] being adapted to be releasably coupled to the linear actuation member” and “the second member being entirely contained within the first member,” as recited in the claims (emphasis added).

Accordingly, withdrawal of the rejection of claims 1-5, 7-10, and 20 under 35 U.S.C. § 102(b) is respectfully requested.

Claims 1-5, 7-11, and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mulhauser et al. in view of Namey, Jr. With respect to claims 5 and 20, these claims have

been canceled without prejudice or disclaimer; thus, this rejection is now moot. With respect to claims 1-4 and 7-11, this rejection is respectfully traversed.

It is respectfully submitted that amended claim 1, and claims 2-4 and 7-11 depending therefrom, are patentable over the Namey, Jr. reference for the reasons discussed above with respect to claims 1-4 and 7-10.

The Mulhauser et al. reference does not make up for the deficiencies of the Namey, Jr. reference. The Mulhauser et al. reference discloses a plunger for a syringe pump. Referring to Figs. 2 and 6, the plunger 28 includes a bottom portion 102 (first member) and a top portion 98 (second member), and the bottom portion 102 is adapted to contact the fluid in the chamber 90. However, the bottom portion 102 is not adapted for attachment to the power screw 84; instead, the top portion 98 engages with the power screw 84 (col. 4, lines 60-63). Further, the top portion 98 is not entirely contained within the bottom portion 102; instead, the bottom portion 102 contains only one end of the top portion 98, and the other end of the top portion 98 is exposed. Thus, the Mulhauser et al. reference does not disclose a piston with “the external distal side [of the first member] being adapted to be releasably coupled to the linear actuation member” and “the second member being entirely contained within the first member,” as recited in the claims (emphasis added).

For these reasons, withdrawal of the rejection of claims 1-5, 7-11, and 20 under 35 U.S.C. § 103(a) is respectfully requested.

Claims 12-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mulhauser et al. in view of Namey, Jr., and further in view of Stevens et al. This rejection is respectfully traversed.

Claims 12-17 depend indirectly from independent claim 1. Accordingly, it is respectfully submitted that claims 12-17 are patentable over the Mulhauser et al. reference in view of the Namey, Jr. reference for the reasons discussed above with respect to claims 1-4 and 7-11.

The Stevens et al. reference does not make up for the deficiencies of the Mulhauser et al. and Namey, Jr. references. The Stevens et al. reference discloses a plunger for a syringe pump. Referring to Fig. 2, the plunger 12 includes a flexible sealing cap 34 (first member) attached to a plunger tip 32 (second member). However, the sealing cap 34 is not adapted for attachment to the plunger 12; instead, the plunger tip 32 is mounted to the plunger 12 (col. 5, lines 42-48). Further, the plunger tip 32 is not entirely contained within the sealing cap 34; instead, the sealing cap 34 contains only the distal end 40 of the plunger tip 32, and the proximal end 38 of the plunger tip 32 is attached to the plunger 12. Thus, the Stevens et al. reference does not disclose a piston with “the external distal side [of the first member] being adapted to be releasably coupled to the linear actuation member” and “the second member being entirely contained within the first member,” as recited in the claims (emphasis added).

For these reasons, withdrawal of the rejection of claims 12-17 under 35 U.S.C. § 103(a) is respectfully requested.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned “VERSION WITH MARKINGS TO SHOW CHANGES MADE.”

If, for any reason, the Examiner finds that the application is other than in condition for allowance and believes that a telephone interview would advance the prosecution of the application, the Examiner is invited to call the undersigned attorney at (818) 576-5291.

Respectfully submitted,

Date: January 16, 2003

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Please replace the paragraph beginning at page 17, line 6 with the following paragraph:

The fluid pressure and occlusion detection systems described in U.S. provisional patent application serial no. [] 60/243,392, (attorney docket no. 0059-0391-PROV) filed October 26, 2000 or in copending U.S. patent application serial no. 09/428,411, filed October 28, 1999, (both of which are incorporated herein by reference in their entireties) or known pressure switch detectors, such as those shown and described with reference to FIGs. 1 and 2, can be used to detect the fluid back pressure associated with the bottoming out of the plunger slide against the piston. A high pressure trigger point of such a pressure switch or occlusion detection system can be set at a point above the relatively flat cross thread force as shown in FIG. 13b. Alternatively, the ramping or the profiles of such back pressure forces can be monitored. When an appropriate limit is reached, the pump system electronics can send a signal to stop the pump motor. Thus the pump drive system is able to automatically detect when the plunger slide has bottomed out and stop the pump motor from advancing the plunger slide.

IN THE CLAIMS:

Claims 5, 6, and 20 have been canceled without prejudice or disclaimer, and claims 1, 2, 18, 21, and 34 have been amended, as follows:

1. (Amended) An apparatus for dispensing a medication fluid comprising:
a reservoir adapted to contain the fluid and adapted for use with a drive system having a linear actuation member; and
a piston comprising:
a first member adapted to be slidably mounted within the reservoir and adapted to form [at least part of] a fluid-tight barrier within the reservoir;
the first member having an external proximate side and an external distal side, the external proximate side being adapted to contact the fluid and being made of a material having a first stiffness, the external distal side being adapted to be releasably coupled to the linear actuation member;
a second member having a first side and a second side, [at least a portion of] the second member being [disposed] entirely contained within the first member and being adapted not to contact the fluid; and
the first side of the second member being adjacent to the external proximate side of the first member and being made of a material having a stiffness which is greater than the first stiffness.
2. (Amended) The apparatus of claim 1 wherein the [second member] first side of the second member is in a generally parallel, spaced-apart relationship with the [first member] external proximate side of the first member.

5. Canceled

6. Canceled

18. (Amended) [The] An apparatus [of claim 12 wherein] for dispensing a medication fluid comprising:

a reservoir adapted to contain the fluid; and

a piston comprising:

a first member adapted to be slidably mounted within the reservoir and adapted to

form at least part of a fluid-tight barrier within the reservoir;

the first member having an external proximate side and an external distal side, the

external proximate side being adapted to contact the fluid and being made

of a material having a first stiffness;

wherein the first member has a cavity and wherein the external distal side of the

first member has an opening leading into the cavity, the cavity comprising:

a first chamber extending from the external distal side into the

cavity; and

a second chamber extending from the first chamber to an internal

proximate wall, the internal proximate wall being disposed

adjacent to the external proximate side;

wherein the first chamber is defined by a generally cylindrically-

shaped first wall extending axially from the external distal

side into the cavity, and the generally cylindrically shaped

first wall has threads; and

wherein the second chamber is defined by:

a generally cylindrically-shaped second wall extending

axially from the generally cylindrically-shaped first

wall into the cavity, the generally cylindrically-

shaped second wall having a radius which is greater

than that of the generally cylindrically-shaped first

wall;

a ledge extending from the generally cylindrically-shaped

first wall to the generally cylindrically-shaped

second wall; and

the internal proximate wall; and
a second member having a first side and a second side, at least a portion of the
second member being disposed within the first member;
the first side of the second member being adjacent to the external proximate side
of the first member and being made of a material having a stiffness which
is greater than the first stiffness;
wherein the second member is disposed within the second chamber.

20. Canceled

21. (Amended) [The] An apparatus [of claim 20] for dispensing a medication fluid
comprising:
a reservoir adapted to contain the fluid;
a piston comprising:
a first member adapted to be slidably mounted within the reservoir and adapted to
form at least part of a fluid-tight barrier within the reservoir;
the first member having an external proximate side and an external distal side, the
external proximate side being adapted to contact the fluid and being made
of a material having a first stiffness; and
a second member having a first side and a second side, at least a portion of the
second member being disposed within the first member;
the first side of the second member being adjacent to the external proximate side
of the first member and being made of a material having a stiffness which
is greater than the first stiffness; and
a drive system including a linear actuation member, wherein the piston first member is
adapted to be releasably coupled to the linear actuation member, and further
wherein the linear actuation member includes a first threaded member and the
piston first member includes a second threaded member adapted to engage the
first threaded member.

34. (Amended) A piston for a reservoir adapted to contain a fluid, the piston comprising:

a first member adapted to be slidably mounted within the reservoir and adapted to form a fluid-tight barrier within the reservoir;

the first member having an external proximate side and an external distal side, the external proximate side being adapted to contact the fluid and being made of a material having a first stiffness; and

[means] a second member adapted to be entirely contained within the first member and not to contact the fluid, the second member being adjacent to the external proximate side of the first member for providing a second stiffness to the external proximate side, the second stiffness being greater than the first stiffness.